

Remarks

Claims 20-22, 28, 29, and 32-49 pending in the subject application. By this Amendment, claims 20, 36, and 46 have been amended to specify that the transition temperature is the austenite finish (A_f) temperature, that the A_f is within the range of human body temperature, and that the spinal deformity to be corrected is a deformity of scoliosis, kyphosis, or lordosis. Claim 45 is cancelled herein, without prejudice, as being of identical scope to claim 44. No new matter has been introduced. Upon entry of these amendments, claims 20-22, 28, 29, 32-44, and 46-49 will be before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Claims 20-22, 28, 29, and 32-49 stand rejected under §112, first paragraph, as lacking written description for reasons set forth at pages 2-3 of the Office Action. Applicants respectfully request reconsideration in view of the above amendments to the claims, which have been made in accord with the Examiner's suggestions, and for which Applicants hereby express their gratitude. The claims now specify that the transition temperature is within the range of human body temperature. Accordingly, Applicants respectfully request withdrawal of this rejection.

Next, claims 20-22, 28, 29, and 32-49 stand rejected under §112, second paragraph, as indefinite by use of the phrase "transition temperature." Applicants respectfully request reconsideration and withdrawal of this rejection in view of their above amendment to the claims specifying that "transition temperature" refers to A_f .

Finally, all pending claims stand rejected under §103(a) as obvious over Drewry *et al.* '527 for reasons set forth at pages 4-5 of the Office Action. Applicants respectfully request reconsideration.

Drewry is entitled "Flexible Spinal Stabilization System and Method" and is primarily concerned with novel anchors and coupling members that can be used in connection with known flexible elongated tethers for dynamic stabilization of spinal motion segments. Although many of the same words found in Drewry are also found in the subject specification, a careful reading of the reference makes clear that Drewry does not teach or suggest any device or method useful for correcting spinal deformities such as scoliosis, kyphosis, or lordosis. It is well established in the law that the teachings of a reference must be considered in their entirety and interpreted as would one of ordinary skill in the art. MPEP 2141.03 (VI). As explained by Professor Kenneth Cheung in his

accompanying Declaration (the "Cheung Declaration"), in this instance a skilled artisan would readily recognize that Drewry's device and method is directed to stabilizing otherwise weakened or unstable motion segments of the spine "that compromise its load bearing and support capabilities. Such pathologies of the spine include, for example, degenerative diseases, the effects of tumors and, of course, fractures and dislocations attributable to physical trauma." (Drewry, column 1, lines 14-18). "Stabilization" is repeatedly used throughout the reference, clearly indicating its primary function. Drewry's invention is particularly directed to stabilizing spinal motion segments to resolve problems affecting disc tissue between vertebrae (see column 1, lines 21-50). At column 1, lines 44-49 Drewry specifies that his invention is directed to providing stabilization device and methods that "allow segmental motion to be maintained after attachment" to the spinal motion segment. At column 3, lines 56-59, Drewry specifies that his stabilization system "allows at least small degrees of spinal motion in the spinal motion segment to which it is attached since system 20 includes an elongate member 80 that is at least partially flexible between adjacent anchors 30." (emphasis added). Drewry's system is known as DYNESYS, and is clearly described in the publication "Dynesys® Dynamic Stabilization System: A Guide for Patients" attached as Exhibit 2 to the Cheung Declaration. As the Cheung Declaration explains, the fact that Drewry's stabilization device and method requires flexibility between adjacent anchors, coupled with the fact that Drewry's elongated tether is taught to be made of polyester or polyethylene or suture as alternatives to superelastic materials makes clear to one skilled in the art that this is a method for stabilizing weakened or unstable portions of the spine. In fact, as attested by Professor Cheung and the accompanying "DYNESYS" publication, Drewry's DYNESYS system is already in clinical use as an adjunct to fusion to treat degenerative slipped discs (spodylolisthesis) in the thoracic, lumbar or sacral regions when there is evidence of resulting neurologic impairment or in the case of a previous failed fusion (pseudarthrosis).

In contrast to Drewry's teachings, the claimed invention is a method of correcting stable spinal deformities such as scoliosis and deformities of kyphosis or lordosis. None of these are mentioned anywhere in Drewry, and one of ordinary skill in the art would find no teaching or suggestion of how to correct such stable spinal deformities in the cited reference. Accordingly, while Drewry uses many of the same words as are found in the subject application, when taken in their

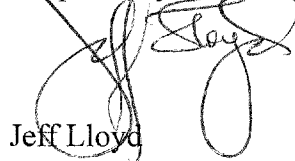
proper context and the reference is read as a whole as the law requires, it is clear to one skilled in the art that Drewry is addressing a completely different problem from that solved by the subject invention. Thus, because Drewry does not teach or suggest the claimed invention, it does not render the claimed invention obvious. Reconsideration and withdrawal of this rejection is respectfully requested.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the claims as currently pending are in condition for allowance, and such action is respectfully requested.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

Respectfully submitted,



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Attachment: Declaration of Kenneth MC Cheung